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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,711	04/05/1999	TAKESHI SAKAI	1/F3511PTUS	1469
513 7590 10/04/2004 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/269,711

Applicant(s)

SAKAI ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2003 has been entered.

2. The claimed method is directed to a method of inducing apoptosis comprising administering an isolated glycerolipid to an individual, wherein the fatty acid(s) which constitute said glycerolipid are those herein defined. Absent a particular definition, "glycerolipid" herein is interpreted as any lipid having the particular fatty acid moieties and glycerol moiety.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 40-43 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winget (US Patent No. 5,620,962, of record).

Winget teaches a composition comprising glyceroglycolipid. See, particularly, the abstract. The glyceroglycolipid is obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget also

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teaches that purity of the glyceroglycolipid is important, i.e., the glyceroglycolipid should be free from other compounds, e.g., phospholipid. See column 1, lines 27-40, particularly, column 1, line 30. Winget further teaches a method for treating inflammation comprising administering the said composition to an animal in need. See column 2, lines 47-55. The fatty acid moieties therein may be C12 to C22 fatty acids. (see, particularly, columns 3-5).

Winget does not teach expressly that the fatty acid moieties are C14, C16, or C18 fatty acids.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glycerolipid isolated from alge with fatty acid moieties being C14, C16, or C18 fatty acids since Winget discloses that Glycerolipid with C14, C16 and C18 fatty acid are useful for therapeutical utilities.

As to the detail biological functions of the glyceroglycolipid, i.e., inducing apoptosis, note, Winget's method would inherent possess the apoptosis inducing process claimed herein. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex*

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parte Novitski, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

2. Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over both Winget (US Patent No. 5,620,962) and, Nojima et al. (JP 60-19716, IDS, AA) in view of Nakai et al. (US Patent 5,672,603), and Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993) for reason as discussed above.

Winget teaches a method for treating inflammation comprising administering glyceroglycolipid to an animal in need. See column 2, lines 47-55, wherein the fatty acid moieties therein may be C12 to C22 fatty acids. (see, particularly, columns 3-5). Nojima et al. teach a method for treating or preventing cancers comprising administering glyceroglycolipid, wherein the fatty acid moieties are C8-C30 fatty acids. See the abstract. Winget further teaches the glyceroglycolipid See, may be obtained by extracting alga with an organic solvent followed by purification on normal phase chromatography. See, particularly, columns 10-12. Winget further teaches that glyceroglycolipid is present in many food products, e.g., lettuce, broccoli, wheat, etc. See column 1, 19-22.

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The primary references do not teach expressly a method of inducing apoptosis, or using glycerolipid wherein the fatty acids are chosen from C14, C16, or C18 fatty acids. The primary references do not teach the employment of acid and/or base in the process of making the glyceroglycolipid.

However, Nakai et al. teaches that apoptosis is a physiological process which may occur under various physiological condition. See, column 1, lines 44-67. e.g., Apoptosis is involved in cancer treatment when the cancer cells are killed. See column 2, lines 15-39. It is concluded that apoptosis regulating compounds or composition are useful as anticancer agent, antiretroviral agent, and therapeutical agent for autoimmune disease, for thrombocytopenia, for Alzheimer's disease and for various types of hepatitis, tumor metastasis inhibiting agent. See, column 4, lines 45-51. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glyceroglycolipid for inducing apoptosis.

A person of ordinary skill in the art would have been motivated to employ glyceroglycolipid for inducing apoptosis because glyceroglycolipids are known to be useful for treating or preventing cancer and apoptosis is known to be a part of physiological process of cancer treating. A person of ordinary skill in the art would reasonably expected that glyceroglycolipid would induce apoptosis since is a part of physiological process of cancer treatment. Furthermore, the employment of acid/base treatment in the process of making the

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glyceroglycolipid is seen to be obvious since the separation/purification of prior art glyceroglycolipids would be expected to increase the concentration of the active glyceroglycolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation. Further, the employment of C14, C16 and C18 fatty acids is seen to be obvious since the prior art disclosed that glycerolipids with such fatty acids are useful for the therapeutical utilities.

3. Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hibino et al. (JP 01160988) in view of Gilchrest et al. (US patent 5,353,440), Giaccia et al. (US Patent 5,646,185) and Nakai et al. (U.S. patent 5,672,603, of record), and in further view of Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993, of record).

Hibino et al teaches that a glycerolipid is useful for treating cancer. See the abstract.

Hibino et al. does not teach expressly to employ glycerolipid from tea, cereal or mushroom for introducing apoptosis, or the fatty acids therein are C14, C16 or C18 fatty acids . However, Gilchrest et al. teaches that natural glycerol lipids (diacylglycerols) are known to be similarly active as physiological activator of PKC. The diacylglyceride PKC activators, including those herein employed. See, column 3, lines 52 bridging column 4, lines 59; column 5, lines 6 to column 6, line 10. Giaccia et al. suggests that PKC activators, including diacylglycerols, are useful in treating cancers. See, particularly, column 6, lines 6-27, and column 12, lines 18-46.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ natural glycerolipids, including those isolated from tea and mushroom, for treating cancers.

4. A person of ordinary skill in the art would have been motivated to employ natural glycerolipids, including those isolated from tea and mushroom, for treating cancers because all the natural glycerolipid are expected to be similarly useful in treating cancer. Regarding the functional limitation, "inducing apoptosis," note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. Further, Nakai et al. teaches that apoptosis is a physiological process which may occur under various physiological condition. See, column 1, lines 44-67. e.g., Apoptosis is involved in cancer treatment when the cancer cells are killed. See column 2, lines 15-39. It is concluded that apoptosis regulating compounds or composition are useful as anticancer agent, antiretroviral agent, and therapeutical agent for autoimmune disease, for thrombocytopenia, for Alzheimer's disease and for various types of hepatitis, tumor metastasis inhibiting agent. See, column 4, lines 45-51. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and

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purification. See page 45. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Therefore, the claimed "method of inducing apoptosis would reading on treating cancers.

Regarding the particular method of isolation and purification of glycerolipid, Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. The employment of acid/base treatment in the process of making the glyceroglycolipid is seen to be obvious since the separation/purification of prior art glycerolipids would be expected to increase the concentration of the active glycerolipids in the instant composition and is considered within the skill of artisan because acid treatment is a well known technique for purification and separation.

5. Claims 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon oil (JP 02273622), in view of Bhuyan et al. and Nakai et al. (U.S. patent 5,672,603, of record), and in further view of Nelson ("Isolation and Purification of lipids from Biological Matrices," in Analysis of Fats, Oil and lipoproteins, Edited by Edward G. Perkins, 1993, of record).

6. Nippon oil teaches that linolenic acid is known to be useful for treating cancer. Nippon oil further teaches a method of treating or preventing cancer, comprising administering to the subject a composition comprising linolenic acid and a tea extract. The linolenic acid may be in the form of glyceride ester. See, particularly, the abstract.

Nippon oil does not teach expressly to employ isolated glycerolipid from tea, cereal or mushroom or for introducing apoptosis.

However, Bhuyan et al. disclosed that linolenic acid is one of the major lipid components in tea.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ glycerolipid isolated from tea as the linolenic acid employed in a anticancer composition.

7. A person of ordinary skill in the art would have been motivated to employ glycerolipid isolated from tea as the linolenic acid employed in a anticancer composition because linolenic acid, known as anticancer agents, is one of the major lipid components in tea, and tea extract is also known to be useful in treating cancers. One of ordinary skill in the art would have reasonable expected that the lipid component comprising linolenic acid moieties from tea extract be useful in treating cancer since linolenic acid and tea extract are known to be useful for treating cancer. Further, one possesses a therapeutical agent in the from of free acid would possess its salts, or ester, including glycerol ester. Regarding the functional limitation, "inducing apoptosis," note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. Further, Nakai et al. teaches that apoptosis is a physiological process which may occur under various physiological condition. See, column 1, lines 44-67. e.g., Apoptosis is involved in cancer treatment when the cancer cells are killed. See column 2, lines 15-39. It is

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concluded that apoptosis regulating compounds or composition are useful as anticancer agent, antiretroviral agent, and therapeutical agent for autoimmune disease, for thrombocytopenia, for Alzheimer's disease and for various types of hepatitis, tumor metastasis inhibiting agent. See, column 4, lines 45-51. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Nelson teaches that acid treatment of materials containing lipid is a well-known technique for lipid separation and purification. See page 45. Therefore, the claimed "method of inducing apoptosis would reading on treating cancers.

Response to the Arguments

Applicants' amendments and remarks submitted September 25, 2003 have been fully considered, but are moot in view of the new ground of rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617